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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION AND INCORPORATED MEMORANDUM TO EXCLUDE THE OPINIONS OF SUZANNE PARISIAN, M.D. AND MEMORANDUM OF LAW IN SUPPORT

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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MOTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court to exclude the opinions of Plaintiffs' expert witness, Suzanne Parisian, M.D. in their entirety.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

The plaintiff has named Dr. Parisian, a well-known plaintiffs' advocate, to offer opinions in this case based upon her review of Bard corporate documents and depositions selected by the plaintiffs' counsel. Dr. Parisian submitted a 282-page report in this case and 49-page supplement. (*See* Report, attached as Exhibit A, and Supplemental Report, attached as Exhibit B (collectively the "Report").)

Dr. Parisian is a seasoned, professional witness who routinely works for plaintiffs in pharmaceutical and medical device litigation. The Court is in the unusual position of having the aid of other courts that have evaluated the same expert on numerous occasions. Many courts have reviewed the reliability and helpfulness of Dr. Parisian's characteristic narrative testimony and sprawling opinions and have excluded them, finding that Dr. Parisian merely provides the plaintiffs' closing arguments, rather than any specialized expertise in regulatory compliance to assist the fact-finder. Her testimony and opinions in this case are no different, and her testimony does not pass the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). First, Dr. Parisian lacks the expertise to offer opinions regarding the design or testing of the IVC filter or causation opinions. Second, her testimony consists of nothing more than factual narratives, legal conclusions, personal opinions, and unsupported speculation — all of which fall outside the scope of proper expert testimony. Finally, even assuming such testimony is permissible, which it is not, Dr. Parisian's opinions are unreliable in that she has not applied sound methodology to reach her conclusions because she cannot to link her conclusions with any applicable FDA regulation. Accordingly, Bard moves to exclude

Dr. Parisian's opinions in their entirety under Rule 702 and the standards set forth in *Daubert* and its progeny.

II. SUMMARY OF CHALLENGES

Because Dr. Parisian's Report is so unwieldy that is serves primarily to frustrate a substantive *Daubert* inquiry, a table of Dr. Parisian's "Summary of Opinions" section and Bard's corresponding challenges is as follows:

OPINION #1: Bard's premarket actions with design and development of the RNF as a permanent IVC filter were inadequate.	• Fails to satisfy Rule 702 or *Daubert*; • Improper speculation and second-guessing the FDA; • Improper state of mind testimony.
OPINION #2: Bard obtained FDA clearance to market the RNF as both a permanent and retrievable IVC filter yet failed to provide physicians and patients with adequate, updated "Instructions For Use" and "Warnings of Risks."	• Fails to satisfy Rule 702 or *Daubert*; • Lacks expertise and foundation as to implanting IVC filters; • Improper legal conclusion; • Lack of relevance or fit to case-specific implanting physicians.
OPINION #3: Bard's actions for post-market oversight continued to permit marketing of the flawed RNF as a permanent IVC filter.	• Fails to satisfy Rule 702 or *Daubert*; • Improper state of mind testimony; • Lack of relevance or fit to case-specific plaintiffs' injuries.
OPINION #4: Bard developed its "Next Generation" of filters based on piecemeal reactive modifications to its flawed original RNF filter platform rather than using quality science and medical device design principles.	• Fails to satisfy Rule 702 or *Daubert*; • Lacks expertise as to device design and engineering; • Lack of relevance or fit to plaintiffs with earlier generation filters.
OPINION #5: Bard's Quality Systems (QS) and post-market monitoring procedures were flawed, helped underestimate patient risk, and permitted continued commercial release of misbranded and dangerous products as supported by Bard's receipt of an FDA 2015 Warning Letter.	• Fails to satisfy Rule 702 or *Daubert*; • Improper legal conclusion as to "misbranded" products; • Improper speculation and second-guessing the FDA; • Lack of relevance or fit to plaintiffs with filters implanted prior to 2015.

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OPINION #6: Bard engaged in aggressive off-label promotion which overstated benefits, downplayed risks, expanded the implanted patient population and failed to adequately warn physicians, patients, and its own sales force of the risks.	• Fails to satisfy Rule 702 or *Daubert*; • Improper legal conclusion; • Improper speculation and second-guessing the FDA; • Improper state of mind testimony; • Lack of relevance or fit to plaintiffs with filters implanted on-label.
OPINION #7: Bard marketed the Recovery Cone Retrieval System as part of the RNF IVCF system to facilitate filter retrieval without having first obtained 510(k) clearance to do so.	• Fails to satisfy Rule 702 or *Daubert*; • Improper speculation and second-guessing the FDA; • Lack of relevance or fit – no plaintiff alleges injury from a Recovery Cone.

In her Supplemental Report, Dr. Parisian states that her opinions regarding the Meridian and Denali filters fit within Opinions 1 through 6 above.

III. COURT OPINIONS ADDRESSING DR. PARISIAN

A few particularly relevant excerpts of other courts addressing Dr. Parisian's nearly identical testimony in other cases is as follows:[1]

[1] Numerous district courts across the country have excluded Dr. Parisian entirely: *Robles v. C. R. Bard, Inc.*, Civil Action No. 5:13-CV-250, United States District Court for the Northern District of Texas, attached as Exhibit C (excluded entirely in an IVC Filter case); *Miller v. Stryker Instruments*, No. CV 09–813–PHX–SRB, 2012 WL 1718825, at *10-12 (D. Ariz. Mar. 29, 2012) (no coherent methodology; unhelpful; legal conclusions; narrative testimony; unqualified to give medical testimony; *ipse dixit*; reliance on after-the-fact events)*; Kaufman v. Pfizer Pharmaceuticals, Inc.*, No. 1:02–CV–22692, 2011 WL 7659333, at *6-10 (S.D. Fla. Aug. 4, 2011) (*ipse dixit*; conclusory opinions; lack of methodology; opinions not tied to FDA regulations or to facts; irrelevant bases; intent/state of mind; outside scope of expertise; outside relevant time period), *reconsideration denied*, No. 1:02–CV–22692, 2011 WL 10501233 (S.D. Fla. Aug. 10, 2011) (narrative testimony; lack of methodology; outside relevant time period); *Hogan v. Novartis Pharm. Corp.*, No. 06 Civ. 0260(BMC)(RER), 2011 WL 1533467, at *2-3 (E.D.N.Y. April 24, 2011) (FDA issues irrelevant; unqualified as to industry standards); *Lopez v. I-Flow Inc.*, No. CV 08–1063–PHX–SRB, 2011 WL 1897548, at *9-10 (D. Ariz. Jan. 26, 2011) (legal conclusions; conclusory; improper state of mind/intent opinions; narrative testimony; bases not connected to conclusions; *ipse dixit*; speculative; outside expertise); *In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323 (S.D. Fla. 2010) (unqualified as to foreign regulations and medical causation; narrative testimony; *ipse dixit*; corporate knowledge and intent; FDA violation testimony conclusory and not tied to regulations; opinions beyond scope of report; improper reliance on internal documents; lack of methodology; speculation; advocate not an expert), *cert. denied*, 2010 WL 2541892 (S.D. Fla. June 22, 2010); *In re Prempro Prod. Liab. Litig.*, 554 F. Supp.2d 871,

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***Lopez v. I-Flow Inc.*, No. CV 08–1063–PHX–SRB, 2011 WL 1897548 (D. Ariz. Jan. 26, 2011)**

- "Dr. Parisian's report is a labyrinth that the Court cannot navigate . . . Dr. Parisian spends 37 pages citing FDA regulations and guidelines but offers no analysis whatsoever to support her opinions….In other sections, Dr. Parisian's report simply presents a narrative of selected regulatory and corporate events and quotations and then leaps to a conclusion without sufficient explanation." *Id*. at *10.

- "Dr. Parisian's report lacks reliability and helpfulness to the jury in other ways as well. In many instances, Dr. Parisian opines as to the knowledge, state of mind, intent or motivations of I–Flow, other Defendants or the FDA itself." *Id*. at *11.

- "I–Flow also contends, and the Court agrees, that many of Dr. Parisian's opinions are beyond her expertise, speculative or too conclusory. (See Parisian Mot. at 3–6, 16–17.) For example, Dr. Parisian concludes that Defendants 'failed to voluntarily and adequately warn health care providers, sales representatives, distributors and patients,' but Dr. Parisian is not qualified to offer such an opinion." *Id*.

***In re Trasylol Products Liab. Litig.*, 709 F. Supp. 2d 1323 (S.D. Fla. 2010), *cert. denied*, 2010 WL 2541892 (S.D. Fla. June 22, 2010)**

- "Dr. Parisian's testimony at the six-hour *Daubert* hearing was problematic in various regards and intensified, rather than alleviated, my concerns. More specifically, when efforts were made to establish the foundation of her opinions, Dr. Parisian retreated into obfuscation and referenced irrelevant FDA regulations while refusing to answer questions." *Id*. at 1339.

***In re Prempro Prod. Liab. Litig.*, 554 F. Supp.2d 871, 879-87 (E.D. Ark. 2008)**

- "In response to Defendants' Motion to Exclude Dr. Parisian's testimony regarding FDA regulations—filed before Dr. Parisian testified during the punitives phase—Plaintiff asserted that Dr. Parisian "will testify further, what those [FDA] regulations require in a particular set of facts and circumstances. Dr. Parisian will also testify that the regulations were violated under this set of facts." She did neither. As discussed in detail above, Dr. Parisian often did nothing, or little, more than read exhibits." *Id*. at 886-87, *aff'd in pertinent part, rev'd in part on other grounds*, 586 F.3d 547, 573 (8th Cir. 2009) ("The admission and the jury's consideration of

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879-87 (E.D. Ark. 2008) (erroneous admission of Parisian testimony required new trial on punitive damages; narrative testimony, *ipse dixit*; testimony not connected to FDA regulations), *aff'd in pertinent part, rev'd in part on other grounds*, 586 F.3d 547, 571 (8th Cir. 2009); *Jacobs v. Caesars Entm't, Inc.*, Civil Action No. 05-0805, 2007 WL 594714, at *4 (E.D. La. Feb. 21, 2007) (insufficient factual basis; unreliable methodology), *reconsid. denied*, 2007 WL 1558717, at *2 (E.D. La. May 30, 2007), *aff'd*, 280 Fed. Appx. 424 (5th Cir. 2008); *Nelson v. C.R. Bard, Inc.*, No. 94cv00416, 2006 WL 6225071 (D.D.C. Sept. 26, 2006) (minute order); *Barnes v. Orthofix Int'l NV*, No. C11–402 JCC, 2012 WL 1931224, at *5 (W.D. Wash. May 23, 2012) (legal conclusions; lack of qualifications; no foundation; speculation).

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Dr. Parisian's testimony, however, amounted to prejudicial error, and thus the appropriate remedy is a new trial.").

- "The Advisory Committee notes to Federal Rule of Evidence 702 read: 'If the witness is relying ... primarily on experience, then the witness must explain how that experience is a sufficient basis for the opinion and how that experience is reliably accurate to the facts.' In pretrial hearings, Judge Jones and I both expressed concern regarding whether Dr. Parisian met this requirement (as evidenced by the repeated requests for citations and explanations). After hearing Dr. Parisian's testimony in the punitive damages phase and reviewing it post-trial, I realize that our concerns were warranted. Dr. Parisian's punitive damages stage testimony reveals 'how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis.' 'An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.'" *Id.* at 887 (citations omitted).

- "During the punitive damages stage of the trial, Dr. Parisian's testimony tracked Plaintiff's legal arguments, and there was very little significant analysis. On numerous occasions, Dr. Parisian declared 'this isn't fair and balanced,' but she provided no explanation…When Dr. Parisian actually elaborated on documents, her testimony did 'no more than counsel for plaintiff [did] in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct.'" *Id.*

IV. ARGUMENT AND CITATION OF AUTHORITY

A. Dr. Parisian is an Advocate, Not an Expert.

Dr. Parisian is a plaintiff's expert who, once permitted to testify under the guise of regulatory expertise, will offer unfounded and inflammatory opinions to argue the plaintiff's case. As one court succinctly noted, "[p]lainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her 'takeaway' or 'take home message' with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise." *In re Trasylol*, 709 F. Supp. at 1351 (S.D. Fla. 2010); *see also U.S. v. Rincon*, 28 F.3d 921, 923 (9th Cir. 1994) (upholding district court's exclusion of expert testimony "more in the role of an advocate and not as a scientifically valid opinion"). After working for the FDA for four years two decades ago, Dr. Parisian opened her own consulting company and has been testifying on behalf of plaintiffs—and only plaintiffs—since 1995. (*See* June 13, 2014, Deposition of

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Suzanne Parisian ("Parisian Dep."), attached as Exhibit D, at 29:12-22.) Dr. Parisian estimates that she has given 180 depositions, and testified in court about 50 times. (*Id.* at 11:10-24.) In every instance but one, she testified against a defendant medical device or pharmaceutical company, including previous testimony against Bard in unrelated litigation. (*Id.* at 40:22-41:3, 63:4-9.) And, Dr. Parisian admitted that, with the exception of the start of her career and the past few years as she nears retirement, she only turned down about one percent of cases with which she was approached. (June 21, 2017, Deposition of Suzanne Parisian ("Parisian Dep. II"), attached as Exhibit E, at 47:2 – 48:14.) Indeed, Dr. Parisian even agreed to offer similar opinions in a Canadian lawsuit, demonstrating that she is indiscriminate in the cases she is willing to take, and that she is willing to offer opinions far beyond the scope of her expertise. She was subsequently excluded in that case. *Anderson v. St. Jude Medical, Inc.*, Court file no. 00-CV-195906CP, Ontario, Superior Court of Justice, attached as Exhibit F.

Here, Dr. Parisian opines that this case is yet another instance of a manufacturer violating the Food, Drug and Cosmetic Act ("FDCA") and FDA regulations by failing to adequately test, monitor, and warn about the risks of its medical product and by failing to disclose safety information to FDA and physicians. (*See e.g.*, Ex. A, Rep. at pp. 15-18.) Although Dr. Parisian's unwieldy report frustrates a substantive *Daubert* analysis, her opinions can be excluded for several discrete reasons as illustrated by examples below.

B. Dr. Parisian is Not Qualified to Opine on IVC Filter Design, Testing, or Causation.

As a threshold matter, Dr. Parisian is not qualified under Rule 702 to offer expert testimony on areas that fall outside her purported regulatory expertise. Dr. Parisian does not have a background in engineering or metallurgy (Ex. D, Parisian Dep., 36:13-25), has never designed an IVC filter or similar medical device (*Id.* at 47:16 – 48:8, 49:4-7), has never tested an IVC filter (*Id.* at 49:8-9), has not conducted any studies about the conditions of the IVC (*Id.* at 160:14-17), has not treated a patient since the 1980s (*Id.* at

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35:17-20), and other than being generally aware of IVC filters, has had no professional involvement with them (*Id.* at 43:17 – 44:13). Yet, Dr. Parisian readily opines on:

- Design - "The examination of the Nitinol wire fractures by [scanning electron microscopy] by Altran indicated ongoing changes in the wire consistent with filter aging as well as corrosion and rubbing. Therefore, as the filter wire age [sic], there will be greater fatigue and increased risk for fracture development." (Ex. A, Rep. ¶ 433.)
- Testing – "Bard's performance of Meridian corrosion testing is flawed and raises significant questions about filter durability and safety." (Ex. B, Supp. Rep. p. 10, heading b.)
- Causation – "Bard's labeling and marketing failed to adequately instruct (IFU) and warn implanting physicians, physicians caring for permanently implanted patients (*e.g.*, surgeons, hematologists, internists, emergency medicine), and patients about the potential post-market risks, including the need for the patient to continue to be monitored for filter complications..." (Ex. A, Rep., at p. 16, Opinion #2.)

Given Dr. Parisian's lack of experience in these areas, as noted above, and the complete lack of any regulatory relevance or analysis, these opinions should be excluded. *See, e.g.*, *In re Trasylol*, 709 F. Supp. 2d at 1345 ("Dr. Parisian also demonstrated at the *Daubert* hearing that she was unable or unwilling to connect her opinions to any valuable regulatory expert analysis and opined on matters that were far beyond her expertise."); *Reece v. Astrazeneca Pharm., LP*, 500 F. Supp. 2d 736, 744-45 (S.D. Ohio 2007) ("It is clear, however, from Dr. Parisian's report, deposition testimony, and testimony at the oral hearing and plaintiff's summary judgment brief that Dr. Parisian seeks to offer testimony and opinions on matters that go well beyond FDA procedures and regulations and her areas of expertise….Specifically, Dr. Parisian seeks to offer the opinions that defendants failed to provide physicians with adequate warnings and directions for the use of Crestor…Dr. Parisian is not qualified to offer such opinions because although she is a medical doctor, plaintiff has not demonstrated that there is anything in Dr. Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure.").

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C. Dr. Parisian's Opinions Fall Outside the Scope of Permissible Expert Testimony.

Dr. Parisian's testimony should be excluded because it consists of nothing more than improper factual narratives, legal conclusions, and speculation as to corporate intent and conduct that invades the province of the court and jury. It is completely devoid of any regulatory analysis or relevance, and is otherwise improper "expert" testimony.

1. Dr. Parisian's "Opinions" Are Improper Factual Narrative Testimony.

Under the façade of regulatory analysis, Dr. Parisian offers, as she has routinely done in the past, a factual narrative laden both with her personal interpretation of documents and unfounded opinions. The 300 pages of Dr. Parisian's Report claim to provide the bases for her opinions regarding Bard's IVC filters. However, these are matters of fact; Dr. Parisian is simply recounting the plaintiff's theory of the case by selectively quoting from non-regulatory documents such as e-mails, memoranda, design files, and depositions with no attempt to connect the facts to any regulatory analysis. Because this testimony improperly invades the province of the jury and is unreliable, it should be excluded. *In re FEMA Trailer Formaldehyde Prod. Liab. Litig.*, Case No. MDL 07-1873, 2009 WL 2169224 (E.D. La. July 15, 2009) (excluding expert testimony merely opining as to the facts of the case because the expert's role was more akin to "the role of an 'über-juror' rather than as an expert [with opinions based on specialized knowledge]"); *Trasylol*, 709 F. Supp. 2d at 1339; 1346 ("Dr. Parisian's 250 page Report...is broad and unwieldy: while each major opinion is followed by statements that are intended to provide the bases for that opinion, there is generally a striking disconnect between these statements and the major opinions…. Dr. Parisian does not analyze the facts; she…regurgitates them and reaches conclusory opinions that are purportedly based on these facts. These facts should be presented to the jury directly…").[2]

[2] The Court may be aware that the reports of Bard's regulatory experts include descriptions of the regulatory history of Bard's IVC filters. Bard believes that its experts, unlike Dr. Parisian, provide substantive regulatory analysis that would actually be helpful to the jury, base their opinions on regulatory documents that actually fall within the scope

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Other courts have excluded nearly identical narratives by Dr. Parisian. The *Fosamax* MDL court, after reviewing Dr. Parisian's 143-page report providing "a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees," rejected such testimony, holding that Dr. Parisian "will not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence." *In re Fosamax Products Liab. Litig.*, 645 F. Supp. 2d 164, 189, 191-192 (S.D.N.Y. 2009). Similarly, the *Prempro* district court described Dr. Parisian's testimony as "track[ing] plaintiff's legal arguments" with "very little significant analysis" and cautioned that such "[a]n expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *In re Prempro*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) (quotations omitted). On appeal, the Eighth Circuit Court of Appeals upheld the *Prempro* district court's post-trial striking of the majority of Dr. Parisian's testimony because, despite being admonished by the court to "relate the testimony to FDA guidelines" Dr. Parisian "often [] simply read the contents of exhibits, thus undermining the asserted basis for expert testimony." *In re Prempro II*, 586 F.3d at 571. *See also, Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 WL 1718825, at *10 (D. Ariz. Mar. 29, 2012) ("Regarding Opinions 1 and 2, whether Defendant marketed its pain pumps for certain indications is a matter of fact to be determined by the jury, and the Court finds that 'scientific, technical, or other specialized knowledge' is not necessary to help the jury make this determination. Indeed, much of Dr. Parisian's report regurgitates facts that should be submitted directly to the jury.").

2. Dr. Parisian's Opinions on Bard's Statutory and Regulatory Compliance Are Inadmissible Legal Conclusions.

It is well established that "an expert witness cannot give an opinion as to her legal conclusion—i.e., an opinion on an ultimate issue of law." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir.2008) (quotation omitted); *In re Rezulin*, 309

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of their experience and expertise, and do not suffer from the same "striking disconnect" between fact and opinion.

F. Supp. 2d 531, 541 (S.D.N.Y. 2004) (experts "may not tell the jury what result to reach or communicate a legal standard — explicit or implicit — to the jury") (internal quotation omitted); *see also*, *Oakberg v. Zimmer, Inc.*, No. CV–03–47–BU–SHE, 2004 WL 5503779, at *2 (D. Mont. Nov. 23, 2004) ("Parisian may not offer opinions relating to the content of FDA regulations, the application of FDA regulations to Defendant's operations, Defendant's alleged violations of FDA regulations, or FDA regulatory clearance or reporting requirements."), *aff'd in pertinent part, rev'd in part on other grounds*, 211 F. App'x. 578, 580 (9th Cir. 2006) (affirming the court "had a proper basis to conclude that the proposed testimony did not rest on a reliable foundation and that the experts were not qualified").

Notwithstanding these clear rules, nearly every opinion in Dr. Parisian's Report improperly seeks to opine that Bard violated the FDCA and related regulations. For example, Dr. Parisian asserts that Bard violated federal standards[3] by failing to adequately study, design, test, validate or monitor its IVC filters and failing to disclose those findings to the FDA; that Bard's "premarket errors and omissions did not comply with FDA regulations, Bard's own internal operating procedures, or acceptable industry practices"; and promoting off-label use. (*See* Ex. A, Rep. at pp. 15-18.) Through her experience, Dr. Parisian has learned to carefully avoid the word "violate" and similar red flags, but she cannot disguise the essence of her intended testimony:

- "[Bard] said the migration resistance was going to be substantial [sic] equivalent to the Simon Nitinol Filter. That's false. And that it was substantially equivalent to the Simon Nitinol Filter, that's false." (Ex. D, Parisian Dep., 217:23 – 218:1.)

[3] As other courts have noted, although Dr. Parisian cites a variety of "applicable regulations" below each opinion heading, she offers no substantive connection between those regulations and her specific opinions. *Trasylol*, 709 F. Supp. 2d at 1349 ("While Dr. Parisian references 21 U.S.C. § 352 and 21 CFR § 201.5 in Opinion # 2, the section 'Bases of Opinions # 1 & # 2' does not analyze Bayer's actions under the cited statute and regulation but rather provides a general background on the FDA process and the role of the FDA. Despite the heading, the section in no way provides an adequate basis for the opinions it is intended to support: the section does not even discuss Bayer's actions with respect to Trasylol, and certainly does not discuss how and why Bayer violated its duties under the relevant statute and regulation.").

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- "It's awareness alone. That you are aware of it, you have a duty…and I don't even have to show [the jury] where the document is saying off-labeled use. It triggers the responsibility of a manufacturer selling a product…So all these things, as a responsible manufacturer, Bard can't do…It seems like they are still marketing retrievable filter in there, and they are not necessarily producing one that's safe and effective. So Bard off-labeled use all over the place..." **(***Id.* at 270:3-4, 8-11, 271:8-9, 17-22.)

- "[T]he company was the one who actually misbranded the product and did not comply with regulations…" (*Id.* at 197:21-23.)

Because Dr. Parisian's opinions impermissibly provide legal conclusions, they should be excluded.

Dr. Parisian's opinions should also be excluded in this case for an additional and independent reason: they are preempted.[4] *See, e.g., Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) ("[e]vidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA"); *Block v. Woo Young Med. Co. Ltd.*, 937 F. Supp. 2d 1028, 1046 (D. Minn. 2013) ("The Court concludes that Dr. Parisian cannot testify regarding an FDA standard of care or standard of conduct, to the extent that such a term indicates compliance with applicable FDA regulations. Implied preemption bars state tort claims that exist solely by virtue of FDCA requirements and include the existence of federal enactments as a critical element…Stating that Woo Young violated an FDA standard of care, or offering similar testimony, will not be permitted. Similarly, Dr. Parisian cannot testify that Woo Young is liable because it promoted its devices in manners inconsistent with the FDCA.") (quoting *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 352–53, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001)).

Dr. Parisian's testimony is only relevant to the plaintiff's failure-to-warn claim for the implicit conclusion that FDA would have required a different warning had defendants

[4] Plaintiffs also may not "bootstrap" alleged failures to investigate and report adverse events to the FDA into a failure to warn or fraud case. *Webster v Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003); *see also Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423-24 (6th Cir. 2005) (plaintiff could not allege that "[D]efendant was negligent per-se in failing to comply with the FDA's conditions of approval" because that "is a disguised fraud on the FDA claim").

timely disclosed the information. (*See, e.g.*, Ex. D, Parisian Dep. at 257:2-3, 7-11 ("They put a label that got them cleared, but it was not an appropriate label…And so the company shouldn't have marketed it in the first place. Once they knew that there was a problem, they should have pulled it. They should have found a product that actually worked or sold their own Simon Nitinol Filter.")) Accordingly, Dr. Parisian's opinions regarding Bard's compliance with the FDCA and related FDA regulations should be excluded here.

3. Dr. Parisian's Opinions Regarding Corporate Intent and Ethics are not Reliable and Would not Assist the Jury.

Dr. Parisian's "opinions" on Bard's state of mind and corporate ethics should be excluded because they are unreliable and do not assist the jury. Additionally, "[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony." *See, e.g.*, *In re Rezulin*, 309 F.Supp.2d at 547. "Further, expert testimony that is merely speculation or pure conjecture based on the expert's impressions of the physical evidence must be excluded as not based on any reliable methodology or scientific principle." *In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007); *see also, In re Fosamax*, 654 F. Supp. 2d at 192 (excluding Dr. Parisian's "conjecture" regarding the "knowledge, motivations, intent, state of mind, or purposes" of pharmaceuticals manufacturer); *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla. 2015) (excluding the similar opinions in a Bard IVC Filter case because "[the plaintiff] fails to demonstrate that these opinions are reliable or relevant to this case. The Engineers themselves do not purport to have any expertise on the relevant ethical or professional standards, and they do not identify the ethical or professional standard on which they base this opinion. As such, these opinions appear to be simply their subjective views on how a medical device manufacturing company should act, and therefore, are due to be excluded as unreliable.").

Here, many of Dr. Parisian's opinions are grounded in conclusory assertions that Bard knew or should have known about alleged safety information at various points in time and Dr. Parisian's conjecture as to why Bard took, or failed to take, certain actions.

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(*See e.g.*, Ex. E, Parisian Dep. II, 82:11 – 83:6 ("[I]t was cleared as a permanent filter and internally the company knew it did not behave as a permanent filter"); *id*. at 110:2 – 111:1 ("[M]y purpose is not to talk specifically about the testing method, but that it was something that the company knew about…But in terms of the company knew [sic] that they had this issue and then what they did in 2010, they relied on the same issue for the Denali…"); Ex. A, Rep. p. 66, heading 3 (unrelated to any regulatory analysis, stating "Acquisition of the new RNF System was intended to expand Bard's IVCF market and increase market share").)

Dr. Parisian also speculates about FDA's knowledge and why the agency took certain actions. (*See* Ex. A, Rep., ¶ 154 ("On top of the traditional concerns about an IVCF, FDA also had new concerns about the new risks associated with intra-procedure recovery of a filter.").)[5] Because Dr. Parisian's opinions amount to nothing more than speculation or conjecture, they should be excluded. *In re Prempro*, 554 F. Supp. 2d at 878-79 ("Plaintiff has conceded that Dr. Parisian will not give an opinion on Upjohn's intent or whether Upjohn's advertisement influenced either Plaintiff or any treating physician").

Similarly, "[p]ersonal views on corporate ethics and morality are not expert opinions." *In re Baycol*, 532 F. Supp. 2d at 1053. Nonetheless, Dr. Parisian testifies on these matters and her opinions should be excluded. (*See* Ex. A, Rep. ¶ 41 ("The duty to ensure the adequacy of the design and development procedures and monitoring practices established, as well as the duty to ensure the adequacy of personnel training and support for these quality processes, rests with a manufacturer's executive management (top-down responsibility)."); Ex. D, Parisian Dep. at 255:1-7 ("[T]he Recovery filter is not substantially equivalent to the Simon Nitinol Filter as a permanent filter. It does say -- it indicates it's a permanent filter and it has not been tested, it had not been designed, it had

[5] Dr. Parisian even speculates as to what authors of medical literature intended. (Ex. A, Rep. ¶ 478) ("The SIR Guidelines were not intended as a truly valid or meaningful comparison for quality assurance by industry…").

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been not developed to be a permanent filter. So right there it begins by saying it is a permanent filter. That's wrong.")); *In re Prempro*, 554 F. Supp. 2d at 883 (excluding Dr. Parisian's opinion that defendant's conduct "would not be appropriate from a public health point of view in terms of women's safety" because this opinion was devoid of regulatory analysis).

D. Dr. Parisian's Testimony is Not Reliable Because It Lacks Methodology.

"One very significant fact [of the *Daubert* analysis] is whether the expert has developed his opinions expressly for purposes of testifying, since a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office. That the expert failed to subject his method to peer-review and to develop his opinion outside the litigation is not dispositive, but if these guarantees of reliability are not satisfied, the expert must explain precisely how he went about reaching his conclusions and point to some objective source to show that he has followed the scientific method." *Cabrera v. Cordis Corp*., 134 F.3d 1418, 1420-21 (9th Cir. 1998) (internal quotations omitted).

When asked to explain her methodology at her deposition—since her report does not— Dr. Parisian provided a vague and generic answer to claim that she used the same methodology she used "at the FDA":

> I would go and I would look at -- basically do a glance at what's on the FDA's Web site, what got cleared, what the predicates are. You know, what -- how did this product evolve in terms of other devices that were similar. So first I establish, how did this product get on the market? And then I would look at medical literature. I would look at discovery documents that are provided, but first I have to figure out in my own head how it got to be on the market, and then I would look at the types of reports that are being given, not just for this device, but for similar devices as to what -- what are physicians writing about it, what's -- so -- and that was how I always began at the FDA . . . I oftentimes will ask, well, what kind of plaintiffs are we seeing? What kind of reports are we seeing? And so it's the same process I've done since -- if you looked at a report I did back at the FDA, it would almost be the same thing. How did this come about? What's the science? And then what are the -- what are the types of reports that are being expressed? And then in this particular case, I would focus specifically on C.R. Bard.

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(Ex. D, Parisian Dep. 74:6-21, 75:9-17.)[6] This is not "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," particularly because Dr. Parisian relies on voluminous documents and testimony she would not have reviewed in the scope of her employment during her four years at FDA. *Guidroz-Brault v. Missouri Pac. R. Co.*, 254 F.3d 825, 830 (9th Cir. 2001) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Dr. Parisian's same "methodology" has been found inadequate by numerous other courts. In *Trasylol*, "Dr. Parisian could not adequately explain her analysis or methodology, neither in her Report, nor at the *Daubert* hearing. All of Dr. Parisian's opinions suffer from this fatal flaw: she recounts Trasylol's regulatory history, the contents of Bayer's internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory expert analysis." *Trasylol*, 709 F. Supp. 2d at 1347. In *In re Prempro II*, the Eighth Circuit Court of Appeals characterized her testimony as "a brief overview of some federal regulations, followed by discussion of specific exhibits, largely devoid of regulatory analysis." 586 F.3d at 570-71 (further noting district court's "frustration that she was not linking her testimony to FDA regulations" and upholding the post-trial striking of "much of Dr. Parisian's testimony and related exhibits"); *see also*, *Miller v. Stryker Instruments*, No. CV 09-813-PHX-SRB, 2012 WL 1718825 at *12 (D. Ariz. Mar. 29, 2012) ("the Court also finds that Dr. Parisian does not have a coherent methodology, and thus her testimony is unreliable. Dr. Parisian states in her report that she uses 'the same methodology [she] was trained to use for the FDA . . . However, the Court is still at a loss as to what this methodology consists of. Indeed, the majority of Dr. Parisian's report

[6] In fact, Dr. Parisian appeared to state that her role at the FDA involved reaching legal conclusions: "And in this context of what I would have done at the FDA. I would have been asked, is this misleading? Is this false? You know, so it's a regulatory context of a post-market sales of products and what a company can say and do in terms of their marketing." (Ex. D, Parisian Dep. at 103:22 – 104:2.)

appears to state facts that could be directly presented to the jury and then make legal conclusions.") (citation omitted). Her methodology is the same here as in these cases, and, therefore, should be excluded.

V. CONCLUSION

Dr. Parisian's opinions are not only inadmissible under Rule 702, but are also unhelpful and unreliable under *Daubert*. Accordingly, the Dr. Parisian's opinions should be excluded in their entirety.

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CERTIFICATE OF SERVICE

I hereby certify that August 24, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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